

X-RAY VIOLATION TRENDS & ENFORCEMENT CASES

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Reviewer

**September
11, 2014**

OBJECTIVES

- Overview of X-ray inspections from 2011 to 2014
- Severity Levels
- Common Violations
- Enforcement Trends

X-RAY INSPECTIONS

2011-2014

- Over 22,000 inspection reports have been submitted since 2011
- 3,566 Notice's of Violation have been issued by Policy, Standards & Quality Assurance
- 16% of all X-ray inspections result in a Notice of Violation from PSQA
- There is virtually zero deviation in the year to year numbers

SEVERITY LEVELS

**Notice
Of
Violation**

SEVERITY LEVEL V

- Least Severe
- Incomplete documentation
- Failure to comply with posting requirements
- Inspections with Severity Level V violations can be closed at the time of inspection with the agreement that the registrant corrects the violations within 30 days

SEVERITY LEVEL IV

- Paperwork violations
- Inspections with Severity Level IV violations can be closed at the time of inspection with the agreement that the registrant corrects the violations within 30 days

SEVERITY LEVEL III

- Minor Health Related or Machine Violations
- Not severe enough to warrant an enforcement action by itself
- Most common example is failure to conduct an Equipment Performance Evaluation at the required interval

SEVERITY LEVEL II

- Health Related Machine Violations
- Common Examples: high entrance exposures, tube stability/tube holding, and unregistered companies
- A notice of violation that contains Severity Level II or Severity Level I violations will be discussed by the Enforcement Review Committee for possible administrative penalties

SEVERITY LEVEL I

- Most severe
- Prohibitive/Unauthorized Use
- Demonstration on Human
- Entrance Exposure double the allowable limits

COMMON VIOLATIONS

DENTAL EQUIPMENT PERFORMANCE EVALUATIONS

■ 25 TAC

§289.232(i)(7)(A):

§289.232(i)(7)

(7) Equipment performance evaluations.

(A) For all dental radiation machines, the registrant shall perform, or cause to be performed, tests necessary to assure proper function of equipment with the indicated standard for each item specified in paragraph (6)(H)-(M) of this subsection. After installation, the tests listed shall be performed every four years.

RADIOGRAPHIC EQUIPMENT PERFORMANCE EVALUATIONS

EPE Frequency
25 TAC §289.227(o)(1):

Type of Machine	Frequency
Radiographic Podiatric use only	<u>4 years</u> from the date of the prior EPE
All other Radiographic	<u>2 years</u> from the date of the prior EPE

RADIOGRAPHIC EQUIPMENT PERFORMANCE EVALUATIONS

When should EPE be performed?

**25 TAC §289.227(o)(2): Within 30
days after ...**

- initial installation of new machines**
- reinstallation of a machine**
- repair of a machine component that
would effect the radiation output**

FLUOROSCOPIC ENTRANCE EXPOSURE RATE

25 TAC §289.227(m)(3)(D)(i):

- **Within 30 days after installation**
- **Within 30 days after any maintenance of the system that might affect the exposure rate**
- **Measurements shall be made annually or at intervals not to exceed 14 months from the date of the prior measurements**

CT RADIATION OUTPUT MEASUREMENTS

25 TAC §289.227(n)(3)(A)(i-iv): Within 30 days after...

- **Installation**
- **Any major maintenance that could affect radiation output**
- **Any major change in equipment operation for example, introduction of a new software package**

CT RADIATION OUTPUT MEASUREMENTS

25 TAC §289.227(n)(3)(A)(i-iv):

Measurements shall be made ...

- Annually or ...
- At intervals not to exceed 14 months from the date of the prior measurements

OPERATING AND SAFETY PROCEDURES

Regulatory Guides for various modalities can be found at:

<http://www.dshs.state.tx.us/radiation/regguide.shtm>

- Regulatory Guide 4.3 – medicine, podiatry, chiropractic
- Regulatory Guide 4.4 – dental
- Regulatory Guide 4.5 – veterinary medicine
- Regulatory Guide 4.6 – accelerators, therapeutic radiation machines, and simulators

OPERATING AND SAFETY PROCEDURES CONTINUED

Documentation that each individual operating a radiation machine must include:

- Name and signature of individual
- The date the individual read the operating and safety procedures
- Initials of the RSO

ENFORCEMENT

Process
&
Trends

ENFORCEMENT PROCESS

- Per 25 TAC §289.205(j)(3)(A) – Administrative penalties may be imposed for severity level 1 or 2 violations. In combination with these higher severity levels or for repeated violations, severity level 3, 4 and 5 violations may also be penalized.
- Upon recommendation from the Enforcement Review Committee, the Enforcement Unit then prepares and mails a **Preliminary Report** letter to the individual with the findings, proposed penalties and options.

ENFORCEMENT PROCESS

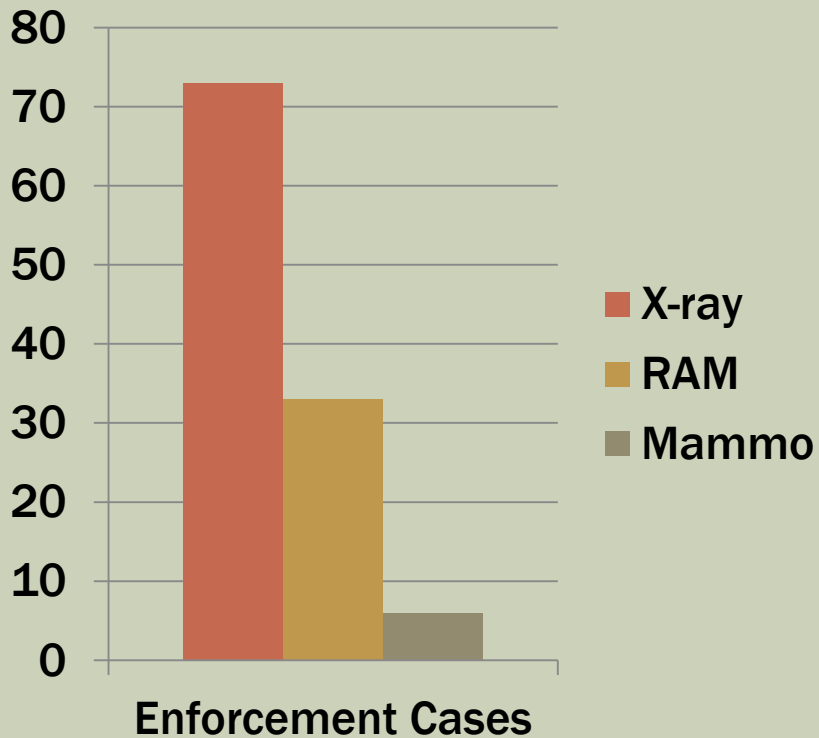
- Options include paying the penalty, requesting an Informal Conference to discuss the violations and penalties, or request a formal hearing in front of an Administrative Law Judge at the SOAH.
- A very high percentage choose the Informal Conference process, either in-person or by telephone, where they will be asked to outline their corrective and preventative actions and present any mitigating circumstances. Following such, agency staff may consider offering a penalty modification or optional binding conditions (i.e., audits, training, probation) for a settlement on the case.

ENFORCEMENT PROCESS

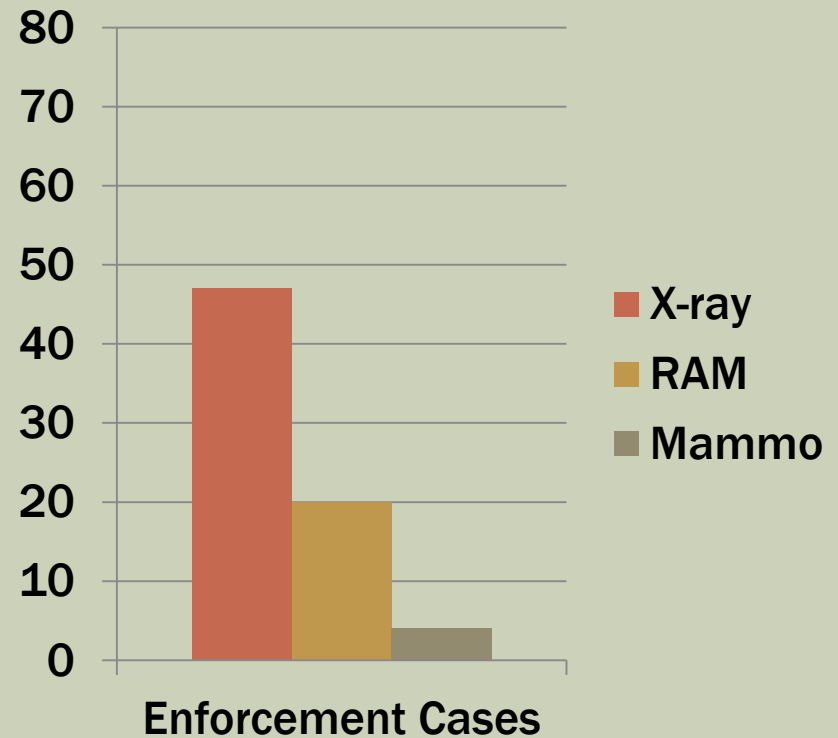
- If no settlement is reached, the case will proceed to a formal hearing at SOAH.
- If an agreed settlement is reached, an **Agreed Order** is prepared for the company's representative or individual to sign and acknowledge the agreed outcomes. The order is final once it is signed by the Department's designee, and any assessed penalty is usually due within 30 days.

X-RAY ENFORCEMENT TRENDS

2013



2014



TYPE OF FACILITIES & ENFORCEMENT

Percentage of Enforcement Cases 2014

